

Deliberative. Comments for discussion on June 17, 2020. Please note: this document conveys the agency's comments as of 6/17/20 and does not indicate a finalized agreement.

EPA requests Hartz's final proposal by 6/22/20, which should address all elements detailed below:

Table: Summary of Proposed Actions and Deadlines		
Hartz Proposal	Details or Additional actions	Agency proposed dates
Dust products		
Missing: proposed date for submitting voluntary cancellation of dust/powder products (Reg. Nos. 2596-78, 2596-79)	Submit voluntary cancellation letter for EPA Registration Numbers (Reg. Nos.) 2596-78, 2596-79.	June 30, 2020
Hartz proposed to provide production reports for dust/powders by September 1, 2020	No need to submit production reports for dusts/powders if production will cease (i.e., cancellation will effective) by July 31, 2020.	N/A
Hartz proposed to cease production of dust/powders by July 31, 2020	Cease production of EPA Reg. Nos. 2596-78, 2596-79.	July 31, 2020: This will be the effective date of cancellation.
Hartz proposed to continue to sell and distribute existing dust/powder stocks through December 31, 2021.	The language that Hartz should use in their proposal to convey this information is, "shall not 'release for shipment,' as that term is defined by 40 CFR § 152.3, after December 31, 2020." This applies to any product for EPA Reg. Nos. 2596-78, 2596-79.	December 31, 2020
Cancelled and Amended Cat Collar Products		
Hartz proposed submitting a voluntary cancellation for EPA Reg. No. 2596-63 (cat collar) July 1, 2020.	Submit a voluntary cancellation letter for EPA Reg No. 2596-63. Submit production reports to confirm that Hartz has not manufactured this product in years. If so, no provisions sale or distribution of existing stocks would be required. Cancellation would be effective immediately (i.e., June 30, 2020), so that no manufacture could occur.	June 30, 2020 rather than July 1 for consistency.
Hartz proposed to file an amended label with the agency on or before September 30, 2020 (Reg. No. 2596-49)	Submit an amendment for EPA Reg. No. 2596-49 to restrict use to cats and kittens at least 12 weeks of age and weighing five pounds or more.	June 30, 2020

Hartz proposed to cease all production for EPA Reg No. 2596-49 (cat collar) under the current label by July 31, 2020, and to continue to sell and distribute existing stocks under the current label for 12 months after EPA's approves the amended label.	<p>Cease production (i.e., cancellation is effective) on July 31, 2020.</p> <p>The language that Hartz should use in their proposal to convey the existing stocks provision is, "shall not 'release for shipment,' as that term is defined by 40 CFR § 152.3, after April 1, 2021." This applies to any product consistent with the current collar label for EPA Reg. Nos. 2596-49.</p>	<p>Cease production (i.e., cancellation is effective) July 31, 2020.</p> <p>Sale and distribution of existing stocks through April 1, 2021.</p>
Redesigned Collar Products (Both Cat and Dog)		
Hartz proposed to submit revised collar designs by September 30, 2020	Submit efficacy data bridging rationale for the collars to be redesigned, EPA Reg. Nos. 2596-50, 2596-62, 2596-83, 2596-84, and 2596-139	June 30, 2020
Missing: date for providing production reports for the following collars: EPA Reg. Nos. 2596-49, 2596-50, 2596-62, 2596-63, 2596-83, 2596-84, and 2596-139	Provide production reports for the calendar years of 2017, 2018, 2019, and 2020 for the following EPA Reg. Nos.: 2596-49, 2596-50, 2596-62, 2596-63, 2596-83, 2596-84, and 2596-139	June 30, 2020
Missing: date for providing report of amount of already-manufactured product awaiting sale or distribution	Provide existing stocks for the following EPA Registration Numbers (Reg. Nos.), 2596-49, 2596-50, 2596-62, 2596-63, 2596-83, 2596-84, and 2596-139	June 30, 2020
Missing: date for official amendment application submission	Submit official amendment applications for redesigned collars, EPA Reg. Nos 2596-50, 2596-62, 2596-83, 2596-84, and 2596-139.	September 30, 2020
Hartz requests permission to continue producing and selling the existing collars under EPA Reg. Nos. 2596-50, 2596-62, 2596-83, 2596-84, and 2596-139 through December 31, 2021 or for one year from the date on which EPA approves the amendment, whichever period is longer. Hartz intends to maintain the current EPA Registration Numbers to avoid	<p>Hartz shall not manufacture any product with the current formulation under EPA Reg. Nos. 2596-50, 2596-62, 2596-83, 2596-84, or 2596-139 after June 30, 2021</p> <p>Hartz shall not "release for shipment," as that term is defined by 40 CFR § 152.3, any additional product consistent with the current collar formulations for EPA Reg. Nos. 2596-50, 2596-62, 2596-83,</p>	<p>Hartz shall cease Production/Manufacturing by June 30, 2021</p> <p>Sale or distribution of existing stocks through December 31, 2021</p>

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discontinuance of state registrations and new state registration fees	2596-84, and 2596-139 after December 31, 2021.	
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Other comments:

- As noted above, the final proposal needs to include a provision for the production of currently registered collars, which is not to exceed the average production rate of the last three calendar years (2017, 2018, and 2019). Production must cease if the current rate has exceeded the average.
- The final proposal will need to include a provision for Hartz to accept returned stocks (collars and dusts) or exchange returned stocks for other products.
- As noted above, the EPA is requesting the final proposal from Hartz by 6/22/20 so that counsel for the registrant begin discussions with the EPA's Office of General Counsel later in the week of June 22 to develop the precise language for Hart's final voluntary request for cancellation.